K122174

NOV 16 2012

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: July 20 2012

Submitter: GE Healthcare Coils (USA Instruments, Inc.)
1515 Danner Dr.
Aurora, OH 44202 USA

Establishment Registration Number: 1529041

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Device: Trade Name: Pediatric Positioner Pad Set

Common/Usual Name: Radiologic patient cradle

Classification Names: 21 CFR 892.1830, Cradle, Patient, Radiologic

Product Code: KXH

Predicate Device(s): K930124, Variant of Octostop and Octopaque
K030317, Model 1300GE-64 – Pediatric Positioner

Device Description: The Pediatric Positioner Pad Set is a positioning device for pediatric patients used with brain, spine, and neurovascular surface coils in Magnetic Resonance Imaging. It is comprised of foam coated in Polyscan. The Pediatric Positioner Pad Set is comprised of seven components: the Base Pad, the Main Pad, the Child Head Pad, the Infant Head Pad, the two Pad Side Supports, and the Head Strap. The Base Pad rests on the MR System table. The Main Pad is then placed on top of the Base Pad. The patient is positioned on top of the Main Pad. The two Pad Side Supports are secured on either side of the patient via Velcro. Lastly, either the Child Head Pad or Infant Head Pad is used with the Head Strap to hold the patient's head in place. There are two sizes for the head pad to accommodate different patient sizes.

The Pediatric Positioner Pad Set is compatible with the GE 1.5T Head, Neck, and Spine Coil (K052621), the Invivo 1.5T 8-Channel High Resolution Brain Array Coil (K013159), the GE 3.0T Head, Neck, and Spine Coil (K093348), and the Invivo 3.0T 8-Channel High Resolution Brain Array Coil (K024352).

Indications for Use: The Pediatric Positioner Pad Set is indicated for use with newborn and infant patients up to 2 years of age or up to 12kg. The Pediatric Positioner Pad Set is indicated for use in conjunction with MR brain, spine, and neurovascular surface coils for use on 1.5T and 3.0T GE MRI Systems for positioning of the pediatric patient.

Technology: The Pediatric Positioner Pad Set is a positioning device for pediatric patients during magnetic resonance imaging. It is used in conjunction with MR surface coils. It is a passive device, containing no electronic components or software.

The Pediatric Positioner Pad Set employs the same fundamental technology as the predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Pediatric Positioner Pad Set complies with voluntary standards. It was designed and developed under the Quality System Regulations of 21 CFR 820 and ISO 13485. The following quality assurance measures were applied to the development of the medical device:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical Tests:

The subject of this premarket submission, Pediatric Positioner Pad Set, required a clinical study on pediatric subjects to support substantial equivalence and to ensure the user needs are met. The clinical images obtained from that study have been included in DICOM format in this submission.

Conclusion:

GE Healthcare considers the Pediatric Positioner Pad Set to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

NOV 16 2012

Ms. Michelle Huettner
Regulatory Affairs Leader, Magnetic Resonance
GE Healthcare Coils (USA Instruments, Inc.)
1515 Danner Drive
AURORA OH 44202

Re: K122174
Trade/Device Name: Pediatric Positioner Pad
Regulation Number: 21 CFR 892.1830
Regulation Name: Radiologic patient cradle
Regulatory Class: I
Product Code: KXH
Dated: October 5, 2012
Received: October 9, 2012

Dear Ms. Huettner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Michael D. O'Hara 2012.11.16 14:06:42 -05'00'

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122174

Device Name: Pediatric Positioner Pad Set

Indications for Use:

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Prescription Use __Yes___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara 2012.11.16 14:08:36 -05'00'

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K122174